

AMENDMENTS TO THE SPECIFICATION

On page 1, line 3 of the specification, please insert the following new paragraph:

(New) This application is a continuation of Application Serial No. 09/757,128, filed January 8, 2001, pending, which is a continuation of Application Serial No. 09/071,757 filed May 1, 1998 which issued on March 13, 2001 as U.S. Patent No. 6,199,556. Application Serial Nos. 09/757,128 and 09/071,757 and U.S. Patent No. 6,199,556 are each incorporated herein, in their entireties by reference thereto, and to which applications we claim priority under 35 USC §120.

Please amend the paragraph beginning on page 2, line 10, as follows:

(Amended) Specifically, the invention includes a retractor or access platform designed to provide the function of a vertical offset of the lower sternum and preferably further comprising attachments to affix complementary surgical ~~instuements~~ instruments, including at least a stabilizer for the beating heart. Generally, the stabilizers are of the type disclosed in PCT Application US 96/15091 (WO/10753), EPO Application 97/02789.1, and USP 5,727,569. The specially designed retractors described herein may also incorporate lights, blowers, suction or other conventional apparatus to facilitate surgical procedure.

Please amend the paragraph beginning on page 2, line 19, of the specification as follows:

(Amended) Figure 1 is a general representation of the ~~thoracic~~ thoracic region of a patient showing the sternum rib cage, and the xyphoid appendage.

Please amend the paragraph beginning on page 3, line 4 of the specification as follows:

(Amended) Figure 4 is ~~a side view of an embodiment of the offsetting retractor assembly of the invention showing a preferred placement of the assembly relative to the rib cage and pelvis of a patient.~~ another embodiment of the offsetting retractor assembly having a different configuration for the support arms.

Please amend the paragraph beginning on page 3, line 7 of the specification as follows:

(Amended) Figure 5 is a side view of an embodiment of the offsetting retractor assembly of the invention showing a preferred placement of the assembly relative to the rib cage and pelvis of a patient.
~~another embodiment of the offsetting retractor assembly having a different configuration for the support arms.~~

Please amend the paragraph beginning on page 3, line 16 of the specification as follows:

(Amended) A preferred surgical procedure to access the beating heart via a xyphoid incision is described as follows. The term “xyphoid incision” refers to a surgical incision proximate to, but not necessarily directly above, the xyphoid appendage. The xyphoid incision of the invention provides a surgical field and access site to the heart that extends through an even opening beneath the sternum and preferably immediately beneath the lowest rib. See also Full-Spectrum Cardiac Surgery Through a Minimal Incision: Mini-Sternotomy (Lower Half) Technique Doty et al. *Annals of Thoracic Surgery* 1998; 65(2): 573-7; Transxyphoid Approach Without Median

Please amend the paragraph beginning on page 5, line 5 of the specification as follows:

(Amended) As described in more detail in the Figures and the following text, a vertically offsetting retractor or access platform is used to engage a portion of the rib cage capable of lifting at least one rib and preferably more than one rib and the sternum. ~~See Figures 2-6: sternum, see Figures 2-6.~~ The term “offsetting” herein is used to describe a manipulation of at least one rib that provides access to the thoracic cavity via the xyphoid incision, generally described herein as “xyphoid access.” Typically, the vertical offsetting procedure ~~is comprised of~~ comprises engaging the lowermost rib with an offsetting retractor or access platform as disclosed herein and lifting at least a portion of the lowermost ribs. This may be accomplished by simultaneously applying force at one or more points about the chest and pelvis, ~~but~~ and preferably includes at least a mechanical force applied ~~to~~ vertically to orient at least a portion of the lower region of the sternum and a rib cage relative to the remainder of the body below the rib cage. As noted, this orientation is most readily achieved by lifting one half of the lower edge of the rib cage, adjacent to the xyphoid appendage using a specially designed surgical

retractor. Although retraction devices such as those described below and in USP 5,730,757 are preferred, other more conventional devices could be adapted, see for example USP 5,026,779; USP 4,726,358; USP 4,852,552; A New Concept in Sternal Retraction: Applications for Internal Mammary Artery Dissection and Valve Replacement, Chaux, et al. *Ann. Thor. Surg.* 42(1986) [473-374] 473-474; A Modified Sternal Retractor, Ancalmo, et al. *Ann. Thorac. Surg.*, 21 (1976) 174; Internal Mammary Retractor, Beg et al. *Ann. Thorac. Surg.*, 39 (1985) 286-287; A Modified Sternal Retractor for Exposure of the Internal Mammy Artery,

Please amend the paragraph beginning on page 6, line 9 of the specification as follows:

(Amended) In addition to the offsetting retractor, additional apparatus are preferred for use in a surgical procedure using xyphoid access. As noted above, a surgical scope may be used to evaluate the position and configuration of the source or target arteries of a coronary artery bypass. When the gastroepiploic artery is the source, direct view through the xyphoid incision may be adequate. However, for most procedures, a scope is preferred, especially for harvesting in an internal mammary artery (LIMA, RIMA) and for completion of the anastomosis ~~anastamosis~~. In least invasive procedures, the scope will be useful in forming the proximal anastomosis ~~anastamosis~~, particularly where a vein graft is used. As noted above, a stabilizer for beating heart surgery is also used. Devices for beating-heart stabilization are described in USP 5,727,569 and PCT Application US 96/15091 (WO/10753) wherein suction is used to ~~attaek~~ attach the stabilizer to the beating heart, and EPO Application 97/02789.1 wherein a mechanical force is applied to the beating heart proximate to the site of a target coronary artery, which are specifically incorporated herein by reference.

Please amend the paragraph beginning on page 8, line 1 of the specification as follows:

(Amended) ~~Referring to Figure 1,~~ Figure 1 illustrates a generic representation of the human thoracic cavity showing the orientation of the sternum, collarbone, and ribs. A xyphoid incision providing access to the beating heart as described above may be made along line A-A. Alternatively, where the incision is aligned along the edge of the lower rib cage, which is particularly preferred for access to the beating heart, the incision may be made along line A-B. As noted, above, the incision should be no longer than approximately 6-7 cm, but may vary depending on the condition of the patient, the orientation of the source and target coronary arteries for the anastomosis ~~anastamosis~~, and other conditions dictated by the clinical condition of the patient.

Please amend the paragraph beginning on page 8, line 9 of the specification as follows:

(Amended) Referring to Figure 2, a retractor assembly or access platform 10 is provided that has the capability to vertically offset ~~orient~~ the lower portion of the rib cage. In one embodiment, the retractor assembly 10 is comprised of a retractor frame 11 which is preferably rigid as in a conventional retractor. In the embodiment shown in Figure 2, the main body at the frame 11 serves as a mounting

point for a retractor arm 12 and a lifting arm 13 which are attached to the frame preferably at a substantially central location relative to the contacts points described below at which the retractor assembly 10 contacts the body. To increase the stability of the frame 11, the frame has at least one support pad affixed to the lower portion of the frame 11 at each contact point 21 where the retractor assembly contacts the body. As shown in Figure 2, contact points 21 are preferably positioned at the extremities of the frame 11 and are configured to rest against the chest or frontal body of the patient to provide maximum stability for the retractor assembly 10. In a preferred embodiment, the frame 11 of the retractor assembly 10 is further comprised of support arms 15 that extend away from the body of the frame 11. In an embodiment where the retractor arm 12 and lifting arm 13 extend away from frame 11 towards the lowermost portion of the rib cage, the support arms 15 extend in like direction, preferably to a point beyond the

Please amend the paragraph beginning on page 10, line 1 of the specification as follows:

(Amended) xyphoid access incision, the retractor arm 12 is inserted in the xyphoid incision to engage the lowermost edge of the lower rib. As in a conventional surgical retractor, the retractor arm 12 may have a spreader member 19 to move the retractor arm 12 to horizontally retract the tissue, bone or other structure engaged by the blade 20 of the retractor arm 12. The spreader member 19 may be a hand-crank, a cable and pulley assembly, or virtually any other mechanical expedient that is typically operated by hand to move the retractor arm 12. The lifting arm 13 preferably moves independently at of the retractor arm 12, but may also be operably connected to a spreader member 19 to provide the offset retraction function. As will be described in more detail in the following embodiments, the retractor assembly 10 may also have associated therewith additional devices to facilitate the surgical procedure performed through the xyphoid incision. A fiber optic 16 light may be attached to the retractor arm 12, the lifting arm 13, the frame 11, or any other convenient point to provide lighting at the surgical field. Additionally, a beating-heart stabilizer 20 is integrally attached by being mounted on a portion of the frame 11, retractor arm 12, or lifting arm 13[...]. The beating heart stabilizer 20 is attached to the frame by means of a dedicated fixture that is located at a point on the retractor assembly 10 that facilitates introducing the stabilizer 20 to the beating heart and fixing the stabilizer 20 in position once the requisite stabilization of the beating heart is achieved. As noted above, the lifting arm 13 provides for vertical offset retraction of a portion of the rib cage, preferably the left rib cage and most preferably the lowest left rib is vertically offset while the horizontal retraction is also provided in a single device that serves as a mount for the beating-heart

stabilizer 20. However, these respective functions can be provided by two discrete retractor devices without departing from the spirit of the invention. The mechanical function of the lifting arm 13 is described in more detail below.

Please amend the paragraph beginning on page 13, line 1 of the specification as follows:

(Amended) beating-heart stabilizer mounting fixture 31 is provided, in this case located directly on the frame 11, for attachment of a beating heart stabilizer 20.